



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2381]

The Food and Drug Administration's Comprehensive, Multi-Year Nutrition Innovation Strategy;
Extension of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice of a public meeting and request for comments, published in the *Federal Register* of June 27, 2018. The notice announced a public meeting entitled "FDA's Comprehensive, Multi-Year Nutrition Innovation Strategy" and invited interested parties to provide information on specific topics related to FDA's Nutrition Innovation Strategy. We are extending the comment period to give interested parties more time to comment.

DATES: FDA is extending the comment period on the notice and its request for comment, published in the *Federal Register* of June 27, 2018 (83 FR 30180). Submit either electronic or written comments by October 11, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 11, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time, October 11, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-N-2381 for “The Food and Drug Administration’s Comprehensive, Multi-Year Nutrition Innovation Strategy; Public Meeting; Request for Comments.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudine Kavanaugh, Food and Drug Administration, Office of Foods and Veterinary Medicine, 10903 New Hampshire Ave., Bldg. 1, Rm. 3218, Silver Spring, MD 20993, 301-796-4647.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of June 27, 2018 (83 FR 30180), FDA announced that it would hold a public meeting entitled “FDA’s Comprehensive, Multi-Year Nutrition Innovation Strategy.” The public meeting, which we held on July 26, 2018, was intended to give interested persons an opportunity to discuss FDA’s Nutrition Innovation Strategy and to provide input on ways to modernize FDA’s approach to better protect public health while removing barriers to industry innovation. We stated that the topics to be addressed at the meeting would include the following:

- Considering using a standard icon to denote the claim “healthy” on food labels.
- Creating a more efficient review strategy for evaluating qualified health claims on food labels.
- Discussing new or enhanced labeling statements or claims that could facilitate innovation to produce more healthful foods and more healthful consumer food choices.
- Modernizing the standards of identity to provide more flexibility for the development of healthier products, while making sure consumers have accurate information about these food products.

- Providing opportunities to make ingredient information more helpful to consumers.
- FDA's educational campaign for consumers about the updated Nutrition Facts label.

See 83 FR 30180 at 30181 to 30182.

The notice invited interested parties to provide information on these and other topics related to FDA's Nutrition Innovation Strategy. We asked that comments be submitted on or before August 27, 2018.

After the public meeting, we received several requests to extend the comment period. The requesters asserted that the time period of 32 days was insufficient to respond fully to FDA's specific request for comments and to ensure comprehensive public input and allow potential respondents to thoroughly evaluate and address pertinent issues.

We have considered the requests and are extending the comment period for another 45 days, until October 11, 2018. We believe that a 45-day extension allows adequate time for interested persons to submit comments while ensuring the continued forward progress of FDA's Nutrition Innovation Strategy.

Dated: August 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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